K000475

AUG 22 2000

SECTION 11 - 510(k) SUMMARY

510(k) application date: February 14, 2000

Applicant: DRAXIMAGE Inc.
16751 Trans Canada Highway
Kirkland, QC
Canada H9H 4J4

Contact: Dr. R.J. Flanagan,
Executive Vice- President
Tel.: (514) 630-7039
Fax: (514) 694-9295
e-mail: rflanagan@DRAXIMAGE.com

Trade name of device: BrachySeed™.

Description of device: Two ceramic beads bearing the radioisotope iodine-125 and a platinum/ iridium rod separating the beads and acting as an X-ray marker are hermetically encapsulated in a welded titanium tube of length 4.4 mm and diameter 0.8 mm. The seeds are available in a range of radiation output intensity levels and must be sterilized before use.

FDA classification:

Name:	Radionuclide Brachytherapy Source
Product Code	KXK
Class of device:	Class II
Regulation number:	21 CFR 892.5730

Special controls: BrachySeed™ will comply with the appropriate controls of the US Nuclear Regulatory Commission (NRC) and of the Atomic Energy Control Board (AECB) of Canada.

Standards met:

ASTM B265 - 99	Standard Specification for Titanium and Titanium Alloy Strip, Sheet and Plate
ISO 2919:1999(E)	Radiation protection - Sealed radioactive sources - General requirements and classification
ISO 9978:1992(E)	Radiation protection - Sealed radioactive sources - Leakage test methods
ANSI/HPS N43.6 -1997	Sealed Radioactive Sources - Classification
21 CFR 820:	Quality System Regulation

SECTION 11 - 510(k) SUMMARY - continued

Predicate devices: Best Industries, Inc. Model 2301, 510(k) K912170
Nycomed Amersham Model 6711, 510(k) K914281
North American Scientific, Inc. Model MED3631-A, 510(k) K972271

Intended use: Draft: BrachySeeds with air kerma strengths up to 1.25U (approx. 1mCi apparent activity) are indicated for permanent interstitial implantation in the treatment of selected localized tumors such as tumors of the head, neck, lung, pancreas, breast, uterus, and prostate. They can be used either as primary treatment or for residual disease after excision of the primary tumor or for recurring tumors. They may also be used at completion of external beam radiation.

BrachySeeds with strengths greater than 1.25U (approx. 1mCi) are indicated for temporary implantation or surface application to treat localized tumors.

Substantial Equivalence:

Considerations in the substantial equivalence demonstration include: capsule type and properties, external imaging properties, the radioisotope, biocompatibility, radiation dose distribution, labeling, and indications for use. Laboratory testing results are included.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2000

Richard J. Flanagan, Ph.D.
Executive Vice President
DraxImage Inc.
16751 Autoroute TransCanada Highway
Kirkland, Quebec
Canada H9H 4J4

Re: K000475
BrachySeed™ (I-25 Brachytherapy Source)
Dated: June 12, 2000
Received: June 15, 2000
Regulatory class: II
21 CFR 892.5730/Procode: 90 KXK

Dear Dr. Flanagan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

SECTION 9 - STATEMENT OF INDICATIONS FOR USE

Page 1 of 1

Applicant: DRAXIMAGE INC.

510(k) Number (if known): K000475

Device Name: BrachySeed™

Indications for Use:

Draft: BrachySeeds with air kerma strengths up to 1.25U (approx. 1mCi apparent activity) are indicated for permanent interstitial implantation in the treatment of selected localized tumors such as tumors of the head, neck, lung, pancreas, breast, uterus, and prostate. They can be used either as primary treatment or for residual disease after excision of the primary tumor or for recurring tumors. They may also be used at completion of external beam radiation.

BrachySeeds with strengths greater than 1.25U (approx. 1mCi) are indicated for temporary implantation or surface application to treat localized tumors.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000475

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.1091)